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No. 85-1710

IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

MALLINCKRODT, INC.,
Petitioner,

v.

SAMUEL F. BENNETT, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the Missouri Court of Appeals, Eastern District

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Motion for Leave to File A Brief As *Amicus Curiae* and Brief of the American College of Radiology As *Amicus Curiae* In Support of the Petition

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Motion of the American College of Radiology for Leave to File A Brief As *Amicus Curiae* In Support of the Petition

The American College of Radiology ("College") hereby requests, pursuant to Rule 36 of the Rules of this Court, leave to file the accompanying brief as *amicus curiae* in support of petitioner.[1] The *amicus* College is an organization of approximately 15,000 United States physicians and radiological physicists who are specialists in radiology, the majority of whom practice nuclear radiology. Low-level ionizing radiation from the types of radionuclides produced by petitioner is used by nuclear radiologists in the diagnosis and treatment of disease. Medical use of radionuclides by a member of the College requires the user to have a specific license from the Nuclear

[1] Pursuant to Rule 36, *amicus* has obtained the written consent of the petitioner, but was denied consent to file by respondents. Petitioner's letter of consent has been filed with the Clerk of the Court.

Regulatory Commission for human use of byproduct material issued pursuant to 10 C.F.R. § 35.12. The regulatory scheme governing medical use of radionuclides is uniquely extensive, detailed and prescriptive. Members of the College practice nuclear radiology in all of the states. They believe that the medical benefits of nuclear radiology should be equally available to the citizens of all of the states, without limitation resulting from differing standards of safety imposed by varying formulations of state tort liability law and federal regulation. The American College of Radiology believes that its views as *amicus* will assist the Court in deciding whether actions under state tort law for alleged economic loss due to radiation should be barred by adherence to federally-mandated safety standards.

The *amicus* American College of Radiology therefore prays that its motion for leave to file a brief in support of the petitioner be granted.

Respectfully submitted,

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QUESTION PRESENTED

Amicus Curiae will address the following question:

Is a state law tort action preempted by the Atomic Energy Act, 42 U.S. § 2011 *et seq.*, when the defendant has operated in compliance with all relevant safety standards established by the Nuclear Regulatory Commission?

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BRIEF OF THE AMERICAN COLLEGE OF RADIOLOGY AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION

INTEREST OF *AMICUS CURIAE*

The American College of Radiology ("College") is a non-profit, California corporation founded in 1924 to advance the science of radiology, improve radiologic service to the patient, study the socioeconomic aspects of the practice of radiology, and encourage improved and continuing education for radiologists and allied professional fields. The College has approximately 15,000 members, a number of whom use radionuclides in the practice of nuclear radiology or conduct research in that discipline. Physicians who utilize radionuclides must obtain a license from the Nuclear Regulatory Commission

("NRC") and comply with extensive prescriptive regulations governing the use of radionuclides in the diagnosis and treatment of disease. 10 C.F.R. parts 31 and 35 (1985).

In the decision for which certiorari is sought here, the Missouri Court of Appeals held that a tort action alleging personal injuries to a class of plaintiffs who worked near a radiopharmaceutical processing facility of petitioner was not preempted, despite the fact that there was no allegation that there had been any occurrence which had violated NRC regulations. The members of the College, who are currently faced with great difficulty and expense in obtaining professional liability insurance coverage under existing rules of law, are understandably very apprehensive about the impact of the Missouri decision upon the continued availability of such insurance for the millions of nuclear radiology procedures carried out on patients in hospitals throughout the country in compliance with federal regulations.[1] A billion-dollar class action against a manufacturer of radionuclides operating within federal regulations can easily be followed by a similar class action by patients against a hospital and its physicians who employ radionuclides within federal regulatory standards. Insurers are well aware of this possibility. If such insurance becomes unavailable or prohibitively expensive, physicians will be forced to discontinue such procedures and patients will be the real losers, a result which should not be ascribed to the intent of Congress in enacting the Atomic Energy Act of 1954, 42 U.S.C. § 2011 *et seq.* or subsequent legislation.

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[1] In 1980, the most recent year for which published data are available, an estimated 6.4 million in-vivo nuclear medicine procedures were performed in U.S. hospitals, a procedure rate of 2.8 per 100 persons. *Radiation Experience Data (RED), Documentation and Results of the 1980 Survey of U.S. Hospitals*, HHS Publication FDA 86-8253, September 1985.

Of even more immediate concern is the question of whether the manufacturers of radionuclides, like the manufacturers of certain types of vaccines, will be forced by tort liability concerns to abandon production, a result which would surely frustrate federal policy and purpose. The probable impact of the decision of the Missouri Court of Appeals upon the practice of nuclear radiology and medicine and upon patients in all of the states ought to be carefully considered by this Court in determining whether to grant the petition. The American College of Radiology, as *amicus*, respectfully requests this opportunity to present its concerns on these issues to the Court.

THE FACTS OF THE CASE

Plaintiff-respondents allege that they represent a class of persons who work adjacent to petitioner's Missouri plant which processes radionuclides for medical use. They allege personal injuries under common law tort theories and claim damages to the members of the class of one billion dollars. The Circuit Court of St. Louis County dismissed on grounds of lack of subject matter jurisdiction and failure to state a claim on which relief could be granted.

The Missouri Court of Appeals reversed. The court reasoned that there was no irreconcilable conflict between federal regulation and "state standards," (apparently referring to state standards yet to be defined on an *ad hoc* basis by juries in tort actions), because it was theoretically possible to both operate within federal regulatory standards and to pay tort damages under state law. The court candidly admitted that "This reasoning may appear to be disingenuous and smack of sophistry . . ." *Bennett v. Mallinckrodt*, 698 S.W. 2d at 860 (1985). In support of its conclusion the court twice cited the District Court opinion in *Cipollone v. Liggett Group*, 593 F.Supp. 1146 (D.N.J. 1984), since reversed in part in *Cipollone v. Liggett Group*, slip op. Nos. 84-5073 and

84-5074 (February 13, 1986). It also considered that there was no frustration of federal objectives in permitting state tort actions, a conclusion it reached without adequate analysis of the probable result of permitting such actions against licensees who were in compliance with federal standards. The court finally concluded that the terms "nuclear incident" and "occurrence" in 42 U.S.C. § 2014(q) must be read to include any claimed cause and effect relationship arising out of the existence of radionuclides. Throughout, the Missouri Court relied upon its reading of this Court's opinion in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) relating to an award of punitive damages.

REASONS FOR GRANTING THE PETITION

The relevant Congressional purpose in enacting the 1959 amendments to the Atomic Energy Act is set forth in 42 U.S.C. § 2021 as follows:

> § 2021.
>
> (a) It is the purpose of this section—
>
> * * *
>
> (3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;
>
> * * *
>
> (5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and
>
> * * *
>
> (b) Except as provided in subsection (c) of this section, the Commission is authorized to enter into

agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under subchapters V, VI, and VII of this chapter, and section 2201 of this title, with respect to any one or more of the following materials within the State—

(1) byproduct materials;

(2) source materials;

(3) special nuclear materials in quantities not sufficient to form a critical mass.

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

* * *

(d) The Commission shall enter into an agreement under subsection (b) of this section with any State if—

(1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and

(2) the Commission finds that the State program is compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

Pursuant to the authority granted by Section 2021, the NRC has entered into agreements with 26 states to

enforce state safety regulations which are consistent with the NRC standards. Missouri is not such a state.

Public concern over the unique physical and biological properties of radioactive materials, including radionuclides, and their concomitant promise of great public benefit led to the unique regulatory system embodied in the Atomic Energy Act, the subsequent amendatory legislation, and the safety standards embodied in the regulations issued by the NRC. These safety standards as they apply to medical radionuclides are also unique, among all bodies of federal regulation of medical activity, in their comprehensiveness, detail and prescriptive effect. 10 C.F.R. parts 31 and 35 (1985). If the Congress had intended the states to be able to impose inconsistent, more stringent safety standards, it could certainly have done so explicitly as it has in other statutes creating regulatory schemes.[2] In explaining what was intended by the requirement of the Act for consistency, the Joint Committee stated:

> "5. The Joint Committee believes it important to emphasize that the radiation standards adopted by States under the agreements of this bill should either be *identical* or *compatible* with those of the Federal Government. For this reason the committee removed the language 'to the extent feasible' in subsection g. of the original AEC bill considered at hearings from May 19 to 22, 1959. The committee recognizes the importance of the testimony before it by numerous witnesses of the dangers of *conflicting*,

[2] In the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, as well as the Federal Water Pollution Control Act, 33 U.S.C. § 1251 *et seq.*, states were granted express authority to impose their own standards to regulate the emission of air and water pollutants respectively. The Federal Water Pollution Control Act provides: "nothing in this chapter shall (1) preclude or deny the right of any state or political subdivision thereof or interstate agency to adopt or enforce (A) *any standard* or limitation respecting discharges of pollutants, . . ." (emphasis added). 33 U.S.C. § 1370. See also, 42 U.S.C. § 7416.

> *overlapping and inconsistent standards in different jurisdictions,* to the hinderance of industry and jeopardy of public safety." (emphasis added). S.Rep. No. 870, 86th Cong., 1st Sess. reprinted in 1959 U.S. Code Cong. & Ad News 2872, 2979.

If the petition for certiorari is not granted and the preemption issues are not thoroughly examined by this Court, the practical effect of the Missouri decision will be exactly what the Congress wished to avoid, i.e. "... conflicting, overlapping and inconsistent standards in different jurisdictions ...", established by *ad hoc* jury verdicts.

This Court has held on several occasions that state law damage claims have a regulatory effect which potentially frustrates congressional objectives and national policies. *Fidelity Federal Savings & Loan Association v. De la Cuesta,* 458 U.S. 141 (1982); *Chicago and Northwestern Transportation Company v. Kalo Brick and Tile Company,* 450 U.S. 311, 326 (1981); *San Diego Building Trades Council v. Garmon,* 359 U.S. 236, 246 (1959). The threat of tort actions and jury verdicts as a mechanism for establishing a "state standard" in each of the 50 states for nuclear physicians, patients, hospitals and insurers, with all of the uncertainty, expense and delay which attends such extensive litigation, may well result in curtailment of highly useful nuclear medical services now available to the public.

The Congressional intent with respect to the availability of nuclear medicine services is made explicit in 42 U.S.C. § 2134(a);

> § 2134.
>
> (a) The Commission is authorized to issue licenses to persons applying therefor for utilization facilities for use in medical therapy. In issuing such licenses the Commission is directed *to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for*

> *such purpose* and to impose the minimum amount of regulation consistent with its obligations under this chapter to promote the common defense and security and to protect the health and safety of the public. (emphasis supplied).

The present NRC standards, which in the absence of an agreement with Missouri are applicable in that state, permit "the widest amount of effective medical therapy possible". The carefully elaborated, highly specific federal regulatory system of the NRC has worked extremely well for the public of medical patients. This fact, in addition to the unique nature of the problems it addresses, argues that it deserves special consideration from this Court. The decision of the Missouri Court of Appeals, based upon reasoning about which it candidly expressed its own concern, is seriously deficient in failing to consider the practical consequences of the rule it prescribes. To ignore such consequences, which will effectively frustrate the objectives of the federal law and wholly subvert the federal regulatory scheme by permitting the substitution of state-determined safety standards, is surely not a "regulatory consequence . . . that Congress was quite willing to accept." *Silkwood*, 464 U.S. at 256.

If the analysis of the Missouri Court is correct, this Court should grant certiorari and affirm that opinion so that the medical community and patients can avoid expensive and protracted litigation on the same tort issues in each of the other states, and can seek appropriate Congressional clarification. It will ill serve the population of medical patients to be required to await a conflict among lower courts for a resolution of the pervasive preemption issues presented by this case.

This case presents this Court with an opportunity to draw a distinction between the right of a state to assess punitive damages in the event of violation of federal standards, established in *Silkwood*, and the effect of the

federal legislation in preempting a private tort remedy in the absence of violation of federal regulatory standards. Such a distinction would be consistent with *Silkwood*, and would preserve both punitive damages and the possibility of state law tort damages. It would have the effect of permitting the "widest amount of effective medical therapy" while reenforcing the desirability of performance within the federal safety standards.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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